

REMARKS

Claims 1-13, 16-41, and 43-49 are pending in the application. Claims 1-12, 22-40, 45, and 46 were withdrawn from consideration pursuant to a Restriction Requirement, leaving claims 13, 16-21, 41, 43, 44, and 47-49 subject to examination. The Information Disclosure Statement submitted on September 7, 2005 was not considered. Claims 13, 16-21, 41, 43, 44, and 47-49 are rejected under 35 U.S.C. § 112, first paragraph; 35 U.S.C. § 102(b); and 35 U.S.C. § 102(e). Further, claims 41, 43, 44, and 49 were rejected under 35 U.S.C. § 112, second paragraph. The rejections are addressed below.

Election/Restriction

The Examiner indicates that claims 17 and 47 are directed to a non-elected species, and thus are withdrawn from consideration. In response, Applicant notes that amendment of claim 17 to specify that $n = 8-12$ (rather than 8) and the addition of claim 47 to specify that $n = 8, 9, 10, \text{ or } 12$ was not considered by them to be in a separate group upon submission of the amendment, as these claims are within the scope of the examined claims. This notwithstanding, Applicant reserves the right to have claims 17 and 47 rejoined if they are to remain withdrawn at this time, in view of linking claim 13, and also reserves the right to petition this requirement. Applicant respectfully requests reconsideration and withdrawal of the requirement, so that claims 17 and 47 can be examined at this time.

Information Disclosure Statement

The Office Action states that the Information Disclosure Statement (IDS) filed on September 7, 2005 fails to comply with the requirements of 37 C.F.R. § 1.98(a)(1) because a Form PTO 1449 is not evident on file. Applicant submits herewith a copy of the IDS filed on September 7, 2005, which includes a Form PTO 1449. Also enclosed is a Patent Office stamped return receipt postcard listing the IDS and Form PTO 1449. Applicant requests that the IDS be considered and that an initialed copy of the Form PTO 1449 be returned with the next Action in this case.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 13, 16-21, 41, 43, 44, and 47-49 are rejected under 35 U.S.C. § 112, first paragraph for lack of enablement. The Office Action states that although the specification enables antigenic amino acids selected from Group 1 (charged), Group 2 (small hydrophobic), Group 3 (large hydrophobic), and Group 4 (hydrophilic), it does not enable for X as groups of four of five or two groups of ten amino acids in any conceivable possible combination. Applicant requests reconsideration and withdrawal of this rejection.

In support of this rejection, the Examiner comments that the claims encompass “a huge combination of different amino acids in a group hence, a potentially huge numbers of mixtures of peptides.” Even with these “huge numbers,” the Examiner states “it is not clearly apparent from the huge scope of the claims the ones that would result in a peptide having a function.” In response, Applicant respectfully submits that because the size of the mixtures/libraries is “huge,” there is an increased chance of identifying relevant peptides in the mixtures/libraries. Further,

even if a mixture/library of the invention was to be screened in a particular experiment and no relevant hits identified, that does not mean that the mixture/library is not useful. Rather, it is standard in the art to have to use multiple libraries to find a desired target molecule, and it cannot be that the claimed libraries would be found to never include such a target.

Applicant further submits that it is unclear what the difficulty could be in selecting groups of amino acids that meet the criteria of the claims and using them to make peptides of the claimed groups and libraries. Those of skill in the art can take, for example, the 20 naturally occurring amino acids and divide them up according to the parameters of the claims. If the chemistry of a particular sequence is such that it is not amenable to generation of a peptide that may be a useful target in a particular assay, then there would be other sequences that are, given the large numbers of possible sequences.

Further in the rejection the Examiner notes that it is not clearly apparent from the huge scope of the claims the peptides that would result in a peptide having a function, and that the specification does not disclose a library that can be screened for a particular purpose/function. In response, Applicant submits that it is a fundamental feature of a library to include many peptides, with many not being relevant to a particular screen. Further, Applicant submits that the libraries of the invention are general, and that there does not need to be a particular purpose/function. Those of skill in the art have been using libraries routinely for many years, and would understand how to apply the presently claimed libraries in screening methods.

The Examiner then proceeds to comment that it is unpredictable which peptides, and which sites therein, are best suited to variations. In response, Applicant notes that the invention does not focus on making variations of known sequences but, rather, concerns sequences (many

of which may be new) that are made using the specified groups of amino acids. Although certain sequences obtained in this manner may possibly result in a peptide that, for example, does not include an epitope recognized by an antibody that is being screened against the library, there are so many different sequences in the mixtures/libraries, which provides the opportunity for such sequences to exist.

The Examiner's comments concerning the degeneracy of the genetic code and the relative integration efficiencies of different amino acids into peptides is not understood, as the mixtures/peptides can be made by use of peptide chemistry and not by translation of nucleic acid templates. Applicant thus requests clarification on this matter.

Finally, the Examiner states "to make a library is known in the art. But the challenge still faced by skilled in the art is the screening of the huge collection of products such that the desired compound with the desired function is obtained." In response, Applicant submits that they are not claiming methods for the identification of a particular type of compound, and that it is standard in the art, in general, to make and use peptide libraries. The mixtures/libraries of the present claims represent a unique, novel, and non-obvious subset of peptide mixtures/libraries, in which the level of variability permitted at each amino acid position is limited in a very particular way. As discussed above, the manner by which this variability is obtained is delineated in the claims.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, first paragraph.

Rejections under 35 U.S.C. § 112, second paragraph

Claims 18, 41, 43, 44, and 49 were rejected under 35 U.S.C. § 112, second paragraph for indefiniteness on several grounds, which are addressed as follows.

Claims 41, 43, 44, and 49 were rejected for indefiniteness, with the Examiner apparently requiring that the claims specify that the claimed kits include instructions for their use. The Examiner cites “conventional wisdom in the art” as a basis for this requirement. In response, Applicant submits that instructions for use are not necessarily required for a kit. For example, there may be a package including multiple kits and there may be one set of instructions in the package that is to be used with respect to each of the individual kits. The kits in such a package may include only the materials to be used, and not the instructions. In view of such an example, Applicant respectfully requests that this rejection be withdrawn. If the rejection is maintained, Applicant requests citation of an authority upon which this rejection is based, so that it can be considered in relation to these claims.

Claims 18 and 49 were rejected for indefiniteness, with the Examiner stating that these claims “are indefinite in the recitation of the ‘library comprises mixtures representing all possible combinations of the groups’, when e.g., there are only two groups.” This rejection has been met by the present amendments of claims 18 and 49, by which the above-quoted statement as it appears in claims 18 and 49 is amended as follows “library comprises mixtures representing all possible combinations of the groups that are present in the mixtures”. No new matter has been added.

Claim 41 was rejected as being unclear as to the type or kind of different tags that can be attached to the different mixtures. In response, Applicant notes that “different” tags are tags that

can be differentiated from one another by some manner. Examples are provided in the application, such as the aluminium barcoded particles described on page 28, lines 3-29.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections under 35 U.S.C. § 102

Claims 13-21 were rejected under 35 U.S.C. § 102(b) as being anticipated by Houghten et al., Nature 354:84-86, 1991; claims 13, 16-21, 41, 43, 44, and 47-49 were rejected under 35 U.S.C. § 102(e) as being anticipated by Fowlkes et al., U.S. Patent No. 6,617,114; claims 13, 16-21, 41, 43, 44, and 47-49 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lynch et al., U.S. Patent No. 5,962,244; and claims 13-21, 47, and 48 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lam et al., U.S. Patent No. 5,858,670. Applicant requests reconsideration and withdrawal of these rejections for the following reasons.

The rejection of claims 13-21 over Houghten et al., Nature 354:84-86, 1991 has been maintained. The Examiner states that certain passages of Houghten describe mixtures that fully meet the claimed mixtures/libraries, but does not do so with sufficient specificity to show that this indeed the case. For example, referring to Table 1 as cited by the Examiner, the peptide mixtures of *a-d* each include “X,” which is not defined. Therefore, it is impossible to determine whether the mixtures of *a-d* comprise amino acids as specified in the present claims, which are selected from four groups of five amino acids, or two groups of ten amino acids, wherein no amino acid is present in more than one group (and for each peptide in the mixture the amino acid at the same position of X_1-X_n is selected from the same group). Rather, it is more likely that the

X's of Houghten covers all amino acids. As to the peptides of *e*, if these represent a group of peptides, they do not meet the limitations of the present claims, as position 6 of the peptides of *e* include more than 10 different amino acids. In another example cited by the Examiner, Figure 1 describes several peptides, each including multiple X residues, which are defined as representing an equimolar mixture of 18 different amino acids. These peptides are not within a mixture of the present claims, which require that each X represent an amino acid selected from four groups of five amino acids or two groups of ten amino acids. Houghten does not describe libraries such as those claimed and, therefore, Applicant requests that this rejection be withdrawn.

Claims 13, 16-21, 41, 43, 44, and 47-49 remain rejected over Fowlkes et al., U.S. Patent No. 6,617,114. The Examiner cites a passage of this patent, which shows that, similar to Houghten, Fowlkes does not anticipate the present claims. In particular, the claims require that each X in the peptides of the mixture be from four groups of five amino acids, or two groups of ten amino acids, wherein no amino acid is present in more than one group (and for each peptide in the mixture the amino acid at the same position of X_1 - X_n is selected from the same group). Based on this, each position can have only one of five possible amino acids or one of ten possible amino acids, and cannot have any one of twenty possible amino acids. The peptides of Fowlkes, in contrast, can include positions that have any amino acid (and not just one of five or one of ten possible amino acids). Fowlkes therefore does not anticipate the present claims.

Claims 13, 16-21, 41, 43, and 44 were rejected as being anticipated by Lynch et al., U.S. Patent No. 5,962,244, and claims 13-21, 47, and 48 were rejected as being anticipated by Lam et al., U.S. Patent No. 5,858,670. The Examiner states that these references meet "the broad claimed mixtures/libraries containing any amino acid sequences." In response, Applicant

submits that, as discussed above, the present claims do not cover libraries that contain “any amino acid sequences.” Rather, the variability of the sequences of the libraries is limited, as is clearly delineated in the claims.

The Examiner also refers to a passage in Lam et al., U.S. Patent No. 5,858,670, describing the selection of particular amino acids to obtain certain secondary structures, such as β -turn, β -sheet, and α -helix structures. When read in the context of the section of the Lam patent in which this passage occurs, it is clear that these particular amino acids are for use in only parts of the peptides, not at each position, and there are random sequences at other positions. Lam states, for example, that certain specific amino acids are selected for use at “specific” (not all) coupling steps (see, e.g., column 9, lines 44-65, and column 7, lines 1-3). As the peptides of the present claims do not include completely random sequences at any positions, as is the case with the peptides of Lam, the Lam patent does not anticipate the present claims.

In responding to prior submitted arguments, the Examiner makes note of the claims not positively reciting what amino acids are in the claimed groups of five amino acids and ten amino acids. In response, Applicant submits that such a recitation is not required, and the lack of recitation does not mean that the claims cover libraries of peptides of any sequence. For example, once a first set of amino acids is selected to be in a group, that selection limits the amino acids that can be in another group. In no instance can there be “any” amino acids, in all groups.

In view of the above, Applicant respectfully requests reconsideration and withdrawal of the rejections for anticipation.

CONCLUSION

Applicant submits that the claims are in condition for allowance, and such action is respectfully requested. If there are any charges not covered or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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